THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

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| LUANN PARKER,<br><br>Plaintiff,<br><br>v.<br><br>AVENTIS PASTEUR INC.<br><br>Defendant. | Case No. C-1-00-766<br><br>Judge Michael Watson<br><br>**REPLY BRIEF OF DEFENDANT AVENTIS PASTEUR INC. IN SUPPORT OF SUMMARY JUDGMENT** |

## I. INTRODUCTION

Defendant, Aventis Pasteur Inc. ("Defendant" or "Aventis") respectfully submits this Reply Brief in response to Plaintiff Luann Parker's ("Plaintiff" or "Parker") Memorandum in Opposition to Aventis' Motion for Summary Judgment and hereby moves the Court to issue an Order dismissing Parker's Complaint with prejudice pursuant to Rule 56 of the Federal Rules of Civil Procedure.

Summary judgment is warranted because Parker has failed to come forward with reliable expert testimony demonstrating that Defendant's FLUZONE® influenza vaccine is capable of causing Parker to suffer from acute disseminated encephalomyelitis ("ADEM"), a rare neurological disorder. Summary judgment is warranted for the reasons described in this Reply Brief, as well as those discussed in Aventis' Motion for Summary Judgment and Memorandum in Support.[1]

[1] Plaintiff also asserts that there is an issue of fact as to whether Plaintiff was properly diagnosed with ADEM in the first instance. See Plaintiff Memorandum at pages 7-8. While that may be true, for purposes of its Motion for Summary Judgment, Aventis has assumed that Plaintiff developed ADEM. Defendant's Motion is predicated on not whether Plaintiff has ADEM, but rather whether there is admissible scientific evidence that ADEM is caused by influenza vaccine.

## II. ARGUMENT

### A. Introduction

This is a products liability action in which Parker alleges that Aventis' FDA approved FLUZONE® influenza vaccine caused her to contract ADEM. Plaintiff alleges that Aventis failed to warn her that FLUZONE® could cause ADEM, and manufactured a defective product for which it should be held liable under theories of negligence and strict liability.

"[W]hether a prescription drug is defective and whether it is the proximate cause of an injury are questions which lie outside the knowledge of lay witnesses." Kerpelis v. Pfizer, Inc., 2004 Ohio 3049, 2004 Ohio App. LEXIS 2900 (2004). Therefore, Parker is required to come forward with reliable and admissible expert testimony establishing general and specific causation in order to prevail on her claims (i.e., that FLUZONE® causes ADEM in general, and in fact caused Ms. Parker to contract ADEM). See U.S. Aviation Underwriters v. B.F. Goodrich Co., 149 Ohio App.3d 569, 575 (Proof of causation is an element of all products liability claims); In re Meridia Products Liability Litigation, 328 F.Supp. 2d 791, 797-98 (finding that causation is element of all product liability claims and explaining that plaintiff must prove general and specific causation); Graham v. American Cyanamid Co., 350 F.3d 507, 510, 513 (6th Cir. 2003) (finding expert testimony required to establish strict product liability under Ohio law in case involving allegedly defective polio vaccine, and finding that only Daubert qualifying testimony is sufficient due to technical and scientific complexity of the subject matter); Kerpelis v. Pfizer, Inc., 2004 Ohio 3049, 2004 Ohio App. LEXIS 2900 (2004) (affirming trial court's dismissal of products liability claims involving pharmaceutical drugs due to plaintiff's lack of reliable expert witness testimony regarding causation).

On June 1, 2004, Aventis moved this Court for an award of summary judgment because Plaintiff was unable to come forward with reliable expert testimony establishing that Fluzone® causes ADEM. Aventis argued that the opinion of Parker's only expert witness, Dr. Griesemer ("Griesemer"), is unreliable because it is not grounded in epidemiology or any other reliable scientific methodology. More specifically, Aventis argued that Griesemer's opinion on causation is unreliable and inadmissible because it (1) is not grounded in epidemiologic studies or data; (2) relies heavily, and almost exclusively, upon a temporal relationship between Parker's receipt of the vaccination and the onset of signs of illness; and, (3) relies upon untested case reports and broad references in medical textbooks, neither of which are legally sufficient to prove causation in courts of law.

On September 27, 2004, Plaintiff filed a Memorandum in Opposition to Aventis' Motion for Summary Judgment asserting that (1) she is not legally required to come forward with epidemiological proof of causation; (2) that she has come forward with reliable expert testimony on the issue of causation, and (3) Dr. Griesemer's opinion on causation is reliable because it is grounded in his review of Plaintiff's medical records, the differential diagnosis of Parker's treating physicians, and excerpts from medical textbooks and case studies.

Parker has attempted to manufacture a genuine issue of material fact on the element of general causation where none exists by (1) submitting an affidavit from Dr. Griesemer that contradicts his prior deposition testimony in violation of law; (2) relying on unauthenticated medical records that contain hearsay and that provide no opinions as to causation to a reasonable degree of medical probability; and, (3) citing to unsupported excerpts from medical textbooks and case studies. All of Parker's efforts are insufficient to rescue Dr. Griesemer's opinion for the reasons described herein.

Moreover, Parker has misrepresented the status of the factual record before the Court.[2] Parker has misrepresented material facts to the Court about the medical records that she attached to her Memorandum in Opposition in a desperate attempt to avoid summary judgment. Parker opens her Memorandum in Opposition by telling the court that each of her treating physicians and an expert at the Centers for Disease Control ("CDC") independently diagnosed her with ADEM caused by the influenza vaccine. This is simply not true. Parker's misrepresentations about the medical records are amplified by the fact that her expert witness, Dr. Griesemer, swore and affirmed in his affidavit that he reviewed them, relied upon them, and agrees with their diagnosis.

Parker directs the Court's attention to a series of unauthenticated medical records to support her position. Careful review of these records reveals, even if they were not inadmissible hearsay, that they do not contain the affirmative causal opinions that Parker claims. For example, Dr. Rorick's letter to Dr. Baker (Exhibit 3 to Parker's Memorandum) is a glaring example of this misrepresentation. Dr. Rorick does not diagnose ADEM and he does not make any affirmative findings concerning the cause of Parker's illness. Instead, Rorick states that he is "uncertain as to the nature of the patient's complaint." He then states, "This appears to be a mild dysequilibrium syndrome, which may represent a post vaccination effect." Rorick admits that he is "uncertain" about his diagnosis, does not diagnose ADEM, and states that the illness (whatever it may be) "may" be a "post vaccination effect". Rorick's letter is not a medical opinion of cause and effect given with a reasonable degree of medical certainty, is not admissible and must be disregarded.

[2] Plaintiff has failed to obtain affidavits or sworn testimony from any treating physician. Plaintiff's reference to unauthenticated medical records and so-called opinions and statements in the medical records is plainly inadmissible hearsay.

Parker's reliance on Dr. Silvania's medical record (Exhibit 6 to Parker's Memorandum) is no more reliable than Dr. Rorick's. Parker refers to the record as proof of the fact that an expert at the CDC confirmed the diagnoses and causal finding of her treating physicians. Again, this is simply not true. Careful review of Dr. Silvania's notes does confirm that she spoke to another physician (Dr. Bridges) who is an expert on the influenza vaccine at the CDC. However, it also reveals that Dr. Bridges told her that Parker's condition "could" be secondary to a "flu shot" and that such a condition would be "very rare". Dr. Bridges then explains that it is just as likely that it could be "coincidental" that Parker simply became ill shortly after receiving the influenza vaccine. In other words, Dr. Bridges confirmed what Aventis has been arguing all along, that there is no real evidence of a causal relationship between the vaccine and the illness in this case.

Parker also directs the Court's attention to her discharge order from the Cleveland Clinic as proof of the fact that the well respected physicians at the clinic diagnosed her illness as ADEM caused by the vaccine. Again, this is not true. Careful review of the record itself (Exhibit 9 to Parker's Memorandum) demonstrates that Dr. Mays was not sure about his diagnosis of ADEM and that it was simply his best guess. Dr. Mays made this clear by placing a question mark "?" next to his diagnosis of ADEM on Parker's discharge order. Again, this is hardly a diagnosis or opinion rendered with a reasonable degree of medical certainty. Moreover, Dr. Mays does not indicate that he was able to confirm any kind of cause and effect relationship between the vaccine and Parker's illness.

The unauthenticated medical records that Parker has attached to her Memorandum in Opposition should be disregarded for the reasons described above as well as those discussed later in this Reply Brief (they violate Rule 56(e), contain hearsay and double hearsay).

Aventis is entitled to summary judgment as a matter of law.

**B. Legal Standards**

**"**Toxic tort cases, are won or lost on the strength of the scientific evidence presented to prove causation." Rider v. Sandoz Pharmaceuticals Corp., 295 F.3d 1194, 1197 (11th Cir. 2002) (affirming trial court's exclusion of unreliable expert opinion testimony on causation and award of summary judgment to defendant). "Toxic tort cases present a unique challenge to the classical conception of causation. Other tort cases, such as slip and fall or car accident cases, feature scenarios where causation is fairly obvious . . . toxic tort cases, however, generally involve less common injuries that often function at the cellular level. The causation inquiry in toxic tort cases is more complicated because the injuries themselves are usually not immediately obvious and the connection between exposure and injury is not a matter of common sense or everyday experience. Moreover, a variety of exposures frequently can associate with the condition." In re Meridia, 328 F.Supp. 2d at 798.

"The courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it." Rider, 295 F.3d 1202. Under Daubert and its progeny federal courts are required to act as gatekeepers to ensure that unreliable scientific guesswork is not mistaken for reliable evidence:

> For many years the standard for admissibility of such evidence was the "general acceptance" test set forth in Frye v. United States, 293 F.1013 (D.C. Cir. 1923). When the Federal Rules of Evidence were enacted in 1975, a question arose as to whether the "general acceptance" test had been supplanted by the reliability test articulated in Rule 702. The question was resolved in three cases decided by the Supreme Court. Daubert v. Merrell Dow Pharm., 509 U.S. 579 (1993); Gen. Elec. Co. v. Joiner, 522 U.S. 136 (1997); Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137 (1999). These cases are commonly referred to as the Daubert trilogy.

Since Daubert, courts are charged with determining whether scientific evidence is sufficiently reliable to be presented to a jury. The Daubert court made it clear that the requirement of reliability found in Rule 702 was the centerpiece of any determination of admissibility. 509 U.S. at 589. The Supreme Court identified four factors used to determine the reliability of scientific evidence: 1) whether the theory can and has been tested; 2) whether it has been subjected to peer review; 3) the known or expected rate of error; and 4) whether the theory or methodology employed is generally accepted in the relevant scientific community. Id .at 593-94.

In Joiner, the Supreme Court established the standard for reviewing trial court rulings of admissibility, and held that such rulings would be made under an abuse of discretion standard. 522 U.S. at 517. The Joiner court also established the important test of analytical "fit" between the methodology used and the conclusions drawn. Id. at 519. The court reasoned that just because a methodology is acceptable for some purposes, it may not be acceptable for others, and a court may not admit evidence when there is "simply too great an analytical gap between the data and the opinion proffered." Id.

In Kumho Tire, the Supreme Court made it clear that testimony based solely on the experience of an expert would not be admissible. 526 U.S. at 157. The expert's conclusions must be based on sound scientific principles and the discipline itself must be a reliable one. Id .at 156. The key consideration is whether the expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Id. The court emphasized that judges have considerable leeway in both how to test the reliability of evidence and determining whether such evidence is reliable. Id .at 151-53.

The Daubert trilogy, in shifting the focus to the kind of empirically supported, rationally explained reasoning required in science, has greatly improved the quality of the evidence upon which juries base their verdicts. Although making determinations of reliability may present a court with the difficult task of ruling on matters that are outside of its field of expertise, this is "less objectionable than dumping a barrage of scientific evidence on a jury, who would likely be less equipped than the judge to make reliability and relevance determinations." Allison v. McGhan Med. Corp., 184 F.3d 1300, 1310 (11th Cir. 1999). The district court did not abuse its discretion in holding that the evidence presented by plaintiff's experts does not meet the standard of reliability.

Rider, 295 F.3d at 1198 (emphasis added).

**C. Aventis is Entitled to Summary Judgment Because Dr. Griesemer's Opinion on General Causation Has No Epidemiologic Basis.**

"Epidemiology, a field that concerns itself with finding the causal nexus between external factors and disease, is generally considered to be the best evidence of causation in toxic tort actions." Rider, 295 F.3d at 1198. Theories of toxic causation that are "unconfirmed by epidemiologic proof cannot form the basis for causation in courts of law." Brock v. Merrill Dow Pharmaceuticals, 874 F.2d 307, 315 (5th Cir. 1989) modified by 884 F.2d 106 (5th Cir. 1989), cert. denied 404 U.S. 1046 (1990), see also Aventis Memorandum in Support of Summary Judgment at pp. 18-20.

Plaintiff's expert, Dr. Griesemer, has conceded that there are no epidemiological studies establishing a causal nexus between FLUZONE®, or any other influenza vaccine and ADEM. Dr. Griesemer's opinion is confirmed by Dr. Glezen. See Affidavit of Dr. Paul Glezen, Exhibit A to Defendant's Motion for Summary Judgment, *see also* Griesemer Dep. at pp. 24, 29, 30, 34. Aventis is entitled to summary judgment because Griesemer's theory of causation is required to be grounded in epidemiology and it is undisputed that no epidemiology exists to support his theory of causation.

Parker argues that it would be impossible for Dr. Griesemer to find epidemiological support for his opinion because the formulation of the influenza vaccine changes slightly every year and, thus, proper studies cannot be conducted. This is simply not true. Dr. Paul Glezen, an epidemiologist that specializes in studying the influenza vaccine has testified that he is not aware of any epidemiological studies establishing a causal relationship between influenza vaccine and ADEM. S*ee* Affidavit of Dr. Paul Glezen, Exhibit A to Aventis Memorandum in Support of Summary Judgment. Moreover, in response to Parker's argument, Dr. Glezen has confirmed that

epidemiological studies have demonstrated that there is not a causal relationship between the influenza vaccine and ADEM. *See* Affidavit of Dr. Paul Glezen (Attached as Exhibit H) at ¶ 5. Dr. Glezen noted that in 1980, H.F. Retailliau of the Centers for Disease Control published an epidemiological study of adverse events following the swine flue vaccine in the *Journal of Epidemiology*. Id. at ¶ 3. The data generated from this study demonstrated that there was no evidence that a person who received swine flu vaccine was at increased risk of developing ADEM compared to a person who had not recently received influenza vaccine. Id. This epidemiological study found the incidence of encephalitis following the receipt of swine flu vaccine was less than expected. Id.

Beginning in 1990, adverse event data following the receipt of influenza vaccine are to be reported to the FDA through the Vaccine Adverse Event Report System ("VAERS") by physicians, individuals and vaccine manufacturers. Id. at ¶ 4. Since then, hundreds of millions of doses of influenza vaccine have been administered in the United States. In recent years, approximately eighty million doses of influenza vaccine have been administered in the United States every year which makes it very possible to pick up rare events such as ADEM. Id. The number of cases of ADEM following influenza vaccine have been insufficient to even suggest a hypothesis that ADEM is caused by influenza vaccine. Id. Dr. Glezen, who has studied influenza and influenza vaccine throughout his professional career, and who has published numerous articles on this subject, has opined that ADEM has never been causally proven to be associated with influenza vaccine. Id.

**D. Dr. Griesemer's Opinion on Causation is Unreliable Because It is Not Based Upon A Sound Scientific Methodology.**

Apart from the lack of epidemiological support, Aventis is still entitled to summary judgment because Griesemer's opinion is not grounded in a sound scientific methodology and is unreliable.

"[I]n establishing a causal chain, epidemiological evidence is just one method of proof . . . epidemiological studies are the primary generally accepted methodology for demonstrating a causal relation between the chemical compound and a set of symptoms or a disease. When an expert does not rely on the primary methodology for establishing causation, then that places a burden on the expert to explain his choice of methodologies." In re Meridia Products Liability Litigation, 328 F.Supp. 2d, 791, 800 (N.D. Ohio 2004) (emphasis added) citing Conde v. Velsicol Chemical Corp., 804 F.Supp. 972, 1025-26 (S.D. Ohio 1992).

Dr. Griesemer explained his methodology during his deposition. Griesemer relied upon the differential diagnosis of Parker's treating physicians, her medical records, the temporal proximity of the vaccination and the onset of illness, and references to medical textbooks and case studies to conclude that Parker suffered from ADEM caused by Aventis' FLUZONE® influenza vaccine. Griesemer's methodology is unreliable as a matter of fact and law for reasons explained below. Moreover, the affidavits, medical records and other materials that Parker attached to her Memorandum in Opposition should be stricken from the record because they violate Rule 56(E) of the Federal Rules of Civil Procedure, contain inadmissible hearsay, and are otherwise not admissible for reasons discussed below.

**1. Dr. Griesemer's Opinion on Causation.**

Dr. Griesemer's opinions are set forth in his deposition testimony and his subsequent affidavit.

Dr. Griesemer did not examine Parker and has not conducted any studies on the influenza vaccine or ADEM. Dr. Griesemer's opinions are based upon his review of Parker's medical records, his clinical experience, references to medical textbooks and case studies, the temporal relationship between the vaccination and onset of illness, and a failed differential diagnosis. See Griesemer Affidavit *in toto*.

**a. Dr. Griesemer's Deposition Testimony.**

Aventis' counsel deposed Dr. Griesemer on July 16, 2003. The transcript of his deposition was filed with this Court on May 20, 2004.

Dr. Griesemer's deposition began with his admission that he has never written any articles on ADEM, and that his familiarity with the disease comes from diagnosing it "from time to time." (Griesemer Dep. at pp. 15, 17.) To this end Griesemer stated:

> I have no particular expertise concerning ADEM that exceeds that of any good neurologist with a broad exposure to clinical disorders.

(Griesemer Dep. at pp. 15-16.)

Furthermore, with regard to the basis for his opinion that FLUZONE® caused Plaintiff to suffer from ADEM, Griesemer admits that he has not examined the Plaintiff, has never spoken to her, and had not reviewed her MRIs, CT scans, or other medical diagnostic test data. (Griesemer Dep. at p. 21.)

According to Griesemer, ADEM is

> a disorder that involves demyelination in regions of the brain. It is a disorder that is typically monophasic, meaning it's got one phase to it, in distinction to a disorder like multiple sclerosis that also involves demyelination of the brain that has multiple occurent phases to it.

(Griesemer Dep. at p. 21.) Griesemer further opines that "ADEM is typically a disorder that follows a viral infection or vaccination." (Griesemer Dep. at. p. 22.) However, Griesemer admits that he did not review or rely upon any scientific, medical or epidemiological studies or literature in formulating his opinion. (Griesemer Dep. at p. 24.) More importantly, Griesemer confirmed on multiple occasions that he is not aware of any epidemiological studies linking the influenza vaccine and ADEM, or establishing a causal relationship between them.

> Q. You're not aware of any epidemiological study in peer reviewed medical literature that has ever indicated that there's a cause and effect relationship between influenza vaccine and ADEM?
>
> A. That's correct.

(Griesemer Dep. at p. 30, see also pp. 24, 29, 34.) Incredibly, Plaintiff's justifications that Dr. Greisemer has relied on his clinical experience, **Griesemer admitted that he has never treated anyone that has contracted ADEM after receiving an influenza vaccine**. (Griesemer Dep. at p. 29.) The truth is that Griesemer has no clinical experience diagnosing ADEM following influenza vaccines.

When asked to explain the basis for his opinion that Defendant's FLUZONE® vaccine caused the Plaintiff to suffer from ADEM, Griesemer repeatedly relies upon the temporal relationship between the Plaintiff's receipt of the vaccine and the initial onset of illness two days later. (Griesemer Dep. at pp. 29, 30, 31, 34-35) Griesemer further states that his opinion is based upon "clinical experience that says, in most cases, ADEM follows viral illness or vaccination" and the fact that he was not aware of any facts which indicate that the Plaintiff had a viral illness or a vaccination other than the FLUZONE® vaccination prior to displaying

symptoms of ADEM[3]. (Griesemer Dep. at pp. 30-31.) When pushed to support his opinion on causation during deposition, Griesemer stated that it was based upon the "preponderance of medical literature" and his experience. (Griesemer Dep. at p. 31.) However, he thereafter admitted that he had not reviewed any studies or medical literature on the influenza vaccine and ADEM and then stated that his opinion was only based upon "current standards of clinical practice." (Griesemer Dep. at p. 32.) Moreover, he once again admitted that there are no pathological or epidemiological studies available that demonstrates that the influenza vaccine can cause ADEM. (Griesemer Dep. at p. 33.) To this end, Griesemer admitted that his conclusion on causation "does not adhere to the scientific level of proof that [he] would submit to a peer reviewed journal for publication."[4] (Griesemer Dep. at p. 33.)

When reviewed in its totality, it is clear that Griesemer's opinion is based primarily on the temporal relationship between the Plaintiff's receipt of the vaccine and the purported onset of symptoms of ADEM two days later, and lacks any real epidemiological, medical or scientific support. (Griesemer Dep. at p. 34.)

Griesemer based his opinion on his belief that there had to be a "trigger" for the onset of ADEM, such as a viral infection or vaccination. However, he again readily admitted that he was unaware of any epidemiology demonstrating that vaccines of any type, let alone FLUZONE,® can cause ADEM. (Griesemer Dep. at pp. 35-36) Griesemer's entire opinion on causation is grounded upon his belief that ADEM only occurs after viral infection or vaccinations. However, Griesemer was unable to substantiate his opinion with anything more than the temporal

[3] A nearly identical expert opinion was excluded by a court in a similar influenza vaccine case. See Lopez v. Wyeth-Ayerst Laboratories, 1996 U.S. Dist. LEXIS 22739 (N.D. Ca. 1996), affirmed, 139 F.3d 905 (1998) (attached as Exhibit A).

[4] When an expert admits that he would not subject his theory or opinion to peer review; courts should be suspicious because peer review is a component of good science, the same is true when an expert, like Griesemer, attempts to differentiate between scientific opinions on causation and medical-legal opinions on causation. See Allen v. Pennsylvania Engineering Corp. , 102 F.3d 194, 198 (5th Cir. 1996).

relationship between the vaccination and the onset of symptoms. (Griesemer Dep. at p. 45.) In fact, Griesemer went so far as to admit that there probably is not sufficient data or evidence to establish a cause and effect relationship between the influenza vaccine and ADEM. (Griesemer Dep. at p. 49.) When pushed, the only support that Griesemer could offer for his opinion, outside of the temporal relationship between the vaccination and the onset of symptoms, was an unsupported passing reference in a neurology textbook stating that ADEM can occur after vaccination against rabies, diphtheria, smallpox, tetanus, typhoid or influenza. (Griesemer Dep. at p. 80.)

**b. Post-Deposition Affidavit.**

Parker has attempted to supplement the testimony that Dr. Griesemer gave under oath during his deposition by submitting an affidavit that contradicts his deposition testimony and unfairly attempts to manufacture questions of fact where none exist in an effort to avoid summary judgment.[5]

Griesemer appears to make five points in his affidavit. First, Griesemer testifies that he reviewed Parker's medical records and then provides a summary of selected out-takes from the records that purport to support his opinion. *See* Griesemer Affidavit at ¶¶ 1-7.

Second, Griesemer testifies that he has reviewed Parker's neuroimaging studies since his deposition and is familiar with literature and studies addressing the link between vaccinations and ADEM, and that based upon the medical record, his review of the literature, and the diagnosis of Parker's treating physicians; he still believes that Parker suffered from ADEM as a result of her influenza vaccination. *See* Griesemer Affidavit at ¶¶ 7-10.

[5] Aventis objects to Parker's attempt to supplement Griesemer's opinion in this manner and believes that the affidavit should be stricken from the record. This issue is addressed in greater detail below.

Third, Griesemer attempts to support his opinion with citations to medical school neurology textbooks and case studies that he did not disclose in his deposition and does not explain in his affidavit. *See* Griesemer Affidavit at ¶¶ 11-16.

Fourth, he acknowledges his reliance upon the temporal relationship between the vaccination and the onset of illness. And fifth, he testifies that he concurs with the differential diagnosis of Parker's treating physicians as reflected in her medical records. *See* Griesemer Affidavit at ¶¶ 18-19.

**2. Griesemer's Reliance on Temporal Relationships as a Basis for a Finding of Causation Renders His Opinion Unreliable as a Matter of Law.**

As described above, a review of Dr. Griesemer's deposition testimony and new affidavit reveals that one of the primary grounds for his opinion on causation is the fact that Parker began to show signs of illness two days after being inoculated. In fact, Dr. Griesemer admitted that this temporal relationship was, in his words, an "important factor" in formulating his opinion on causation. (Griesemer Dep. at p. 35; see also Griesemer Affidavit at ¶ 18) While Dr. Griesemer classifies this temporal relationship as an "important factor," he was unable to identify any other basis for his opinion during his deposition, other than a passing reference in a textbook which indicated that ADEM may follow a viral infection or vaccination.

Courts across the country have recognized that "an opinion based primarily, if not solely on temporal proximity does not meet Daubert standards." Roche v. Lincoln Property Co., 278 F. Supp. 2d 744, 764-65 (E.D. Vir. 2003), citing Cavallo v. Star Enterprise, 892 F. Supp. 756 (E.D. Vir. 1995), affirmed in relevant part, 100 F. 3d 1150 (4th Cir. 1996), In re Breast Implant Litigation, 11 F. Supp. 2d 1217, 1232-33 (D.Col. 1998), In re Swine Flu Immunization Products

Liability Litigation, 533 F. Supp. 567 (D. Col.1980), In re Agent Orange Products Liability Litigation, 611 F. Supp. 1223, 1249 (E. D. N.Y. 1985).

The Second Circuit Court of Appeals recently affirmed a lower court's award of summary judgment to a defendant in a products liability case involving a vaccine because there were no epidemiological studies to support the plaintiff's expert's opinion and the opinion was based "largely on the temporal proximity" of the vaccination to the onset of symptoms. See Washburn v. Merck & Co., Inc., 2000 U.S. App. LEXIS 8601 (2nd Cir. May 1, 2000) (attached as Exhibit B). In doing so, the Washburn court affirmed the lower court's finding that the expert testimony on causation was not reliable because it was based on "little more than temporal correlation" and was therefore properly excluded because it was unsubstantiated. Washburn, *6. The Washburn court cited the opinions of the United States District Court for the Southern District of Ohio and the Sixth Circuit Court of Appeals in Conde for the proposition that expert testimony on causation is unreliable and inadmissible when it is based on little more than temporal correlation. See Conde, 804 F. Supp. 972, 1023 (S.D. Ohio 1992), affirmed 24 F. 3d 809 (6th Cir. 1994).

In addition to its decision in Conde, the Sixth Circuit Court of Appeals has made similar rulings in a multitude of other cases. In Novak, the Court reversed an award of judgment for the plaintiff because the plaintiff failed to come forward with reliable expert testimony establishing that the swine flu vaccine caused the illness that killed the plaintiff's husband and the plaintiff's experts "relied heavily on the relatively short period between Novak's inoculation and development of his sickness." Novak, 865 F. 2d at 722. In doing so, the Novak Court cited its previous decision in another swine flu vaccination case, Hassler v. United States, 718 F. 2d 202, 205 (6th Cir. 1983), Cert. Denied, 469 U.S. 817 (1984), where it found that a temporal

relationship could not support a finding of causation because any connection between the vaccination and illness was "merely conjectural."

Dr. Griesemer's expert opinion on causation is unreliable and inadmissible since it is based primarily upon the temporal correlation between Parker's receipt of the vaccination and the onset of signs of illness days later.

**3. Griesemer's Reliance Upon References in Medical Textbooks and Case Reports as a Basis for a Finding of General Causation is Unreliable as a Matter of Law.**

In addition to temporal proximity, Dr. Griesemer refers to medical case reports and excerpts from neurology textbooks as the basis for the opinions on causation that he rendered during his deposition and his subsequent affidavit. See Griesemer Dep. at pp. 80, Griesemer Affidavit at ¶ 11, 12, 16. Dr. Griesemer fails to elaborate on these sources or explain how they support his opinion. Moreover, these types of sources have been universally found to be unreliable as the basis of an expert opinion on causation in cases with facts that are nearly identical to those of this case.

"Generally, Courts have excluded expert causation testimony that is based upon such anecdotal or case reports. . . [because] they simply describe reported phenomena without comparison to the rate at which the phenomena occur in the general population or in a control group; do not isolate and exclude potentially alternative causes; and do not investigate or explain the mechanism of causation." Lopez v. Wyeth-Ayerst Laboratories, 1996 U.S. Dist. LEXIS 22739 (N.D. Ca. 1996) (Granting summary judgment to influenza vaccine manufacturer on plaintiff's claims that vaccine caused neurological injury), affirmed, 139 F.3d 905 (9th Cir. 1998) (Attached as Exhibit A), see also In re Breast Implant Litigation, 11 F. Supp.2d 1217, 1233 (D. Co. 1998) (rejecting opinion testimony based upon "clinical experience" and "review of the

medical literature" and noting that the mere possibility of a causal relationship is insufficient for a causation opinion under Daubert).

"A case report is simply a doctor's account of a particular patient's reaction to drug or other stimulus . . . Case reports make little attempt to screen out alternative causes for a patient's condition. They frequently lack analysis, and they often omit relevant facts about the patient's condition. Hence, "causal attribution based on case studies must be regarded with caution . . . though case reports demonstrate a temporal association . . . the association is not scientifically valid proof of causation." Glastetter v. Novartis Pharmaceuticals Corp., 252 F.3d 986, 989-990 (8th Cir. 2001); See also Soldo v. Sandoz Pharmaceuticals Corp., 244 F.Supp. 2d 434, 537-41; Turner v. Iowa Fire Equipment Co., 229 F.3d 1202, 1209 (8th Cir. 2000) citing Willert v. Ortho Pharm. Corp., 995 F.Supp. 979, 981 (D. Minn. 1998); Casey v. Ohio Med Prod., 877 F.Supp. 1380, 1385 (N.D. Cal. 1995); Schmaltz v. Norfolk & Western Ry. Co., 878 F.Supp. 1119, 1122 (N.D. Ill. 1995).

An expert's reliance upon case reports to support a causation opinion "is contrary to both good scientific practice and the Daubert case law." Fabrizi v. Rexall Sundown, Inc. 2004 U.S. Dist. LEXIS 9859 (W.D. PA. 2004) (attached as Exhibit C), citing Soldo, Id.; See also Rider, 295 F.3d at 1199; In re Meridia, 328 F.Supp. 2d at 808.

The same problems that make case reports unreliable for purposes of analyzing medical causation issues have caused courts to find that references to medical textbooks usually do not constitute a reliable basis for an expert's opinion on causation. Soldo, 244 F.Supp. 2d at 542; Glastetter, 252 F.3d at 990. Accordingly, Dr. Griesemer's opinion is unreliable and inadmissible.

**4. Griesemer's Differential Diagnosis is Unreliable.**

Dr. Griesemer testified that his opinion is based in-part on a "differential diagnosis." Griesemer testified that he considered the fact that Parker did not have neurological ailments prior to receiving the influenza vaccine, along with the temporal relationship between her vaccination and illness, and reviewed her medical records to arrive at his conclusion. Griesemer Affidavit at ¶ 10, Griesemer Dep. *in toto*.

In order to perform a proper differential diagnosis "a physician begins by "ruling in" all scientifically plausible causes of the plaintiff's injury. The physician then "rules out" the least plausible causes of injury until the most likely cause remains. The final result . . . is the expert's conclusion that a defendant's product caused (or did not cause) the plaintiff's injury." Glastetter, 252 F.3d at 989.

Griesemer's differential diagnosis is unreliable as a matter of law for no less than three reasons.

First, a proper differential diagnosis is grounded in the principle that all of the potential causes that are "ruled in" are "at least capable of causing the disease in question." Meister v. Medical Engineering Corp., 267 F.3d 1123, 1129 (D.C. Cir. 2001). Here, Dr. Griesemer purports to rely on excerpts from a few neurology textbooks and isolated case reports to "rule in" Aventis' FLUZONE® vaccine as a potential cause of Parker's ADEM. This is insufficient as a matter of law.

A similar opinion was offered by a plaintiff's expert witness in Meister and was excluded by the trial court. The D.C. Circuit affirmed the trial court's decision to exclude the expert's testimony and explained:

> Whether Meister's condition was atypical or not, Dr. Borenstein failed to show any nexus between her atypical symptoms and her

> breast implants; the mere simultaneous existence of the two clearly is not an appropriate methodology. His reliance on case reports, temporal methodology, and Meister's atypical symptoms are not sufficient to show that silicone breast implants are capable of causing scleroderma, and therefore his reliance on differential analysis does not meet *Daubert* standards. Regarding the literature that he reviewed, Dr. Borenstein did not testify that any of the studies had actually concluded that scleroderma was caused by silicone breast implants. At most, his testimony revealed that the authors indicated that their observations support or "suggest" a role for silicone in the etiology of scleroderma.

Meister, 267 F.3d at 1129. The same is true of Griesemer's opinion.

Second, Griesemer admitted that he did not examine Parker and noted that his "differential diagnosis" and opinion on causation are grounded in his review of Parker's medical records and the diagnosis and statements of Parker's treating physicians (as reflected in Parker's medical records).

A differential diagnosis based solely on a review of medical records, with no accompanying physical examination, is inherently limited and unreliable. The reliability of the foundation of a physician's ability to eliminate other potential causes turns in part on whether a physician conducted a physical examination of the injured party. For example, in Fabrizi, the plaintiff alleged that the defendant's St. John's Wort caused her to suffer from cataracts. Fabrizi's expert, Dr. Lamperski, purported to perform a differential diagnosis to arrive at his causation opinion, but failed to examine the plaintiff and relied heavily on medical records and statements made by other physicians to arrive at his opinion. The Court concluded that Lamperski's opinions were lacking substance under Rule 702 and Daubert. More specifically, the Court noted that "Dr. Lamperski cannot establish general causation through the inadmissible opinions and testimony of Dr. Roberts . . .expert testimony that simply parrots the opinion of another does not assist the trier of fact." Fabrizi at pp. *31. Further, the Fabrizi court concluded

that Lamperski's heavy reliance on medical records and the statements of others rendered his opinions "insufficient as a matter of law" when coupled with his failure to examine the plaintiff. Fabrizi at pp. * 34, citing In re Paoli R.R Yard PCB Litigation, 35 F.3d 717, 758-59, (3d Cir. 1994). This is especially true in this case where, as indicated above, the treating physicians have never at any time and in any admissible manner offered any opinions as to medical causation. Dr. Griesemer has failed to examine Parker and impermissibly relies on his review of her medical records and the inadmissible statements of other physicians.

Third, careful review of Griesemer's affidavit and deposition testimony reveals that he did not conduct his own differential diagnosis, but relied upon the differential diagnosis of Parker's treating physicians. However, Parker's treating physicians were clearly more concerned with identifying and treating her condition than they were with identifying the specific substance that caused her condition. See Turner, 229 F.3d at 1208 (explaining the difference between a "differential diagnosis" performed by a treating physician to discern the probable identity of a medical condition or disease so that it can be treated and a "differential diagnosis" performed to determine the medical and legal cause of the condition or disease and affirming the trial court's exclusion of expert opinion testimony on causation because it was unreliable). Again, the same is true here. The fact that Dr. Griesemer relies upon the diagnosis of Parker's treating physicians does not make his opinion on causation reliable because diagnosing the identity or type of an illness and determining its medical/legal cause are not equivalent acts.

Aventis is entitled to summary judgment because Dr. Griesemer's opinion on causation is unreliable. His opinion is unreliable because it is not grounded in epidemiology or any other sound scientific or medical methodology that is valid to prove causation in a court of law. To admit Dr. Griesemer's opinions, the Court would have to make several scientifically unsupported

leaps of faith in the causal chain. "The Daubert rule requires more. Given time, information, and resources, courts may only admit the state of science as it is. Courts are cautioned not to admit speculation, conjecture or inference that cannot be supported by sound scientific principles. The courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it." Rider, 295 F.3d 1202, citing Rosen v. Ciba-Geigy Corp., 78 F.3d 316, 319 (7th Cir. 1996). Defendant is entitled to judgment as a matter of law.

Moreover, none of the treating physicians upon whose medical records Greisemer relies even opines on medical causation. For example, Dr. Rorick stated "I am uncertain as to the true nature of the patient's complaint. This appears to be a mild dysequilibrium syndrome which may represent a post-vaccination effect." (See Exhibit 3 to Parker's Memorandum.) Further, the Cleveland Clinic Discharge Order reflects a principal diagnosis of "? Acute Demyelinating Encephalomyelitis," with no indication of cause. See Exhibit 9 to Parker's Memorandum. This hardly reflects an opinion to a reasonable degree of medical probability. Tellingly, Plaintiff has not presented an affidavit or sworn statement from any treating physician opining as to whether the influenza vaccine has caused Parker's ADEM or any other injury.

### E. The Court Should Strike the Affidavits, Medical Records and Other Materials That Parker Attached to Her Memorandum in Opposition.

#### 1. The Court Should not Consider and Must Strike the Affidavit of Dr. Griesemer Because it Contradicts his Prior Deposition Testimony.

Dr. Griesemer was deposed by defense counsel in this matter.[6] Aventis subsequently moved the Court for summary judgment arguing that Griesemer's opinion, as reflected in his deposition, was unreliable for a variety of well-documented reasons, and that the Court must therefore award summary judgment to Aventis.

[6] His testimony is described at length in previous sections of this brief and Aventis' Memorandum in Support of Motion for Summary Judgment and the transcript of his deposition was filed with the Court.

Parker responded to Aventis' motion by filing a Memorandum in Opposition that refers to the Affidavit of Dr. Griesemer. Griesemer's Affidavit restates much of what he said during his deposition, but also includes new testimony; citation to new sources; and new grounds for his opinion on causation. The Court should not consider Griesemer's affidavit when ruling on Aventis' Motion for Summary Judgment and must strike it from the record.

Generally, deposition testimony is given more weight than testimony provided by affidavit, as it affords opposing counsel an opportunity for cross-examination. "To the extent that the subsequent affidavit contradicts the witness' prior sworn testimony, courts will disregard these averments." Knotts v. Black & Decker, Inc., 204 F.Supp. 2d 1029, 1045 n.6 (N.D. Ohio 2002) (citing multiple Sixth Circuit authorities and Moore's Federal Practice).

Courts routinely strike or refuse to consider these types of affidavits in cases involving facts similar to those *sub judice*. For example, the plaintiff in Graham, a toxic tort case involving the polo vaccine, attempted to avoid summary judgment, like Parker, by getting a previously deposed expert witness to submit an affidavit that attempted to explain his prior deposition testimony. The trial court refused to consider the affidavit and granted summary judgment to the defendant, the Sixth Circuit affirmed. See Graham, 350 F.3d at 509, see also Peck v. Bridgeport Machines, Inc., 237 F.3d 614, 619 (6th Cir. 2001), citing Reid v. Sears Roebuck & Co., 790 F.2d 453, 460 (6th Cir. 1986), First Bank of Marietta v. Hartford Underwriters Insurance Company, 1999 U.S. App. LEXIS 29273 (6th Cir. 1999) (citing Rule 56(e) and multiple case authorities) (attached as Exhibit D).

If a person who has been examined at length in deposition could raise an issue of fact simply by submitting an affidavit contradicting his own prior testimony, this would greatly diminish the utility of summary judgment for screening out sham issues of fact. Lindstrom v.

A.C. Products Liability Trust, 2003 U.S. Dist. LEXIS 12545 (N.D. Ohio 2003) (attached as Exhibit E), citing Reid, Id.

Accordingly, the Court should strike Griesemer's affidavit and consider only his deposition testimony when ruling on Aventis' Motion for Summary Judgment.

**2. The Court Should Not Consider and Must Strike the Medical Records that Parker Attached to her Memorandum in Opposition Because They Violate Rule 56 (e), are Not Authenticated, and Contain Inadmissible Hearsay.**

Exhibits 2 through 9 to Parker's Memorandum in Opposition are an array of uncertified and unauthenticated medical records from Bethesda Hospital, River Hills Health Care and the Cleveland Clinic Foundation. The records are not certified and Parker failed to attach or submit affidavits from records custodians or other qualified sources to authenticate the records.

"Rule 56(e) requires that sworn or certified copies of all papers be attached to an affidavit. Thus, to be considered in a summary judgment proceeding, an exhibit must be authenticated." Phelps v. Coy, 164 F.Supp.2d 961, 969 n.9 (S.D. Ohio 2001) (refusing to consider unauthenticated exhibits and granting summary judgment); see also Knight v. Schulman, 102 F.Supp.2d 867, 871 (S.D. Ohio 1996); Ril v. Troutman, 950 F.Supp. 268, 269-70 (D. Mo. 1996) (refusing to consider medical records in summary judgment proceeding and granting summary judgment on liability to defendant), Ulman v. Anderson 2004 U.S. Dist. LEXIS 7119, *13 n9 (D. N.H. 2004) (attached as Exhibit F), Cummings v. Roberts, 628 F.2d 1065, 1068 (8th Cir. 1980) (uncertified medical records should not be considered), Casey v. Riedel, 195 F.Supp.2d 1122, 1133 n2 (S.D. Iowa, 2002), Wright & Miller 10 A Federal Practice & Procedure, § 2722**.**

Parker's medical records must also be stricken from the record because they contain hearsay. For example, Exhibit 6 is a medical record from Bethesda Hospital in which Dr.

Silvania purports to document statements made by another physician, Dr. Carolyn Bridges, concerning the cause of Parker's neurological dysfunction. Parker relies heavily on Dr. Bridges' purported statement to Dr. Silvania when opposing Aventis' Motion for Summary Judgment. Moreover, Dr. Griesemer states that he relied upon Dr. Bridges' statement in rendering his opinion. Griesemer Affidavit at ¶ 10, 19. Parker has not obtained an affidavit from Dr. Bridges herself and has not disclosed her as a potential witness. Furthermore, Dr. Bridges only allegedly said that Plaintiff's severe ataxia "could be secondary to the flu shot or it could be coincidental." At no time does she give her opinion as to a reasonable degree of medical probability. Reliance of Dr. Bridges statements is plainly improper on several levels.

A court, upon a motion for summary judgment, can consider only materials that would be admissible at trial. Thus, a party opposing summary judgment cannot use hearsay or other inadmissible evidence to create a question of fact. Wiley v. U.S., 20 F.3d 222, 226 (6th Cir. 1994); Sperle v. Mich. Dept. Corr., 297 F.3d 483, 495 (6th Cir. 2002).

The issue of whether a physician's statements to another physician are admissible at trial was squarely addressed by the Sixth Circuit Court of Appeals on October 15, 2004 in Field v. Trigg County Hospital, Inc., 2004 U.S. App. LEXIS (6th Cir. 2004) (attached as Exhibit G). There, the plaintiff brought medical malpractice causes of action against a physician and hospital. At trial, the Court permitted the defendant physician to testify that he telephoned another physician at another hospital to consult with him on the plaintiff's diagnosis and treatment, and that the consulting physician told him that he was treating the patient properly.

The Sixth Circuit called this "classic hearsay" which is inadmissible and found that the hearsay exception for statements made for the purpose of medical diagnosis or treatment under

Federal Rule of Evidence 803(4) did not apply because it only covers statements made by a patient to a treating physician.

The same is true here. Parker and Griesemer rely heavily on an unauthenticated medical record that contains a statement that was allegedly made by one physician to another (Dr. Bridges to Dr. Silvania) during consultation about the diagnosis and course of treatment of a patient (Parker). This is "classic hearsay." Moreover, just as in Trigg, the statement does not fit within the medical diagnosis hearsay exception of Rule 803(4) because the statement was not made by a patient to a treating physician (Parker to Silvania); it was made by Dr. Bridges to Dr. Silvania and is inadmissible hearsay that must not be considered by the Court when ruling on Aventis' Motion for Summary Judgment.

## V. CONCLUSION

The Court should issue an order awarding Aventis summary judgment and dismissing Parker's Complaint with prejudice because all of her claims require her to come forward with reliable expert testimony on the element of causation. Dr. Griesemer's opinion on causation is unreliable and inadmissible for the reasons described in Aventis' Motion for Summary Judgment; Memorandum in Support; and this Reply Brief. Parker has attempted to manufacture issues of fact where none exist by submitting inadmissible documents and affidavits. The Court must strike these materials from the record and award summary judgment to Aventis.

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

The undersigned attorney for Aventis certifies that a copy of the foregoing Reply Brief of Defendant Aventis Pasteur Inc. in Support of Motion for Summary Judgment was served via the Court's electronic filing system upon Firooz T. Namei, Esq., and Roger W. Weseli, Esq., McKinney & Namei Co., L.P.A., 15 East Eighth Street, Cincinnati, Ohio 45202, this 1st day of November, 2004.

/s/ Michael A. Snyder
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